



Ente Certificazione Macchine srl

SGQ N° 141A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

CERTIFICATO n. PGH-2020-006 rev.2
CERTIFICATE No. PGH-2020-006 rev.2

Ente Certificazione Macchine srl Certifica che l'Organizzazione
Certify that the Organization

Pall Medical – A Division of Pall International Sàrl

Avenue de Tivoli 3, 1700 Fribourg, Switzerland

Per il seguente campo di attività
For the following activities

Design, development, procurement, testing, management of manufacturing, placing on the market (selling as legal manufacturer) of:

- non-active filtration medical devices for the prevention of contamination and cross-contamination during patient treatment in hospital environment
- non-active medical devices for cord-blood/stem cell collection, processing, transplant and freezing systems
- non-active medical devices for cell harvest filter systems
- non-active medical devices for anaesthetic gas delivery

Technical area 1.1.A

Ha implementato e mantiene un
Has implemented and maintains a

Sistema di Gestione per la Qualità
Quality Management System

che soddisfa i requisiti delle seguenti norme
which fulfils the requirements of the following standards

EN ISO 13485:2016

Data di prima emissione
Date of first issue **12/01/2021**

Data di emissione
Date of issue **12/01/2021**

Data di revisione
Date of revision **16/01/2024**

Data di scadenza
Expiry date **11/01/2027**

Firma autorizzata
Authorized signature


(Luca Bezzoni - Technical Director)

Ente Certificazione Macchine srl

Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)

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CERTIFICATO ISO 13485
CERTIFICATE ISO 13485

Rev.01 del 02/12/2022

SG13_M02 Certificato ISO 13485



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Allegato al CERTIFICATO n. PGH-2020-006 rev.2 Annex to CERTIFICATE No. PGH-2020-006 rev.2

Elenco dei siti inclusi in questo certificato: List of sites covered by this certificate

Sito Site	Indirizzo Address
Registered place of business and main site	Avenue de Tivoli 3, 1700 Fribourg, Switzerland
Medical R&D and regulatory affairs	Global Life Science Solutions Operations UK Ltd, 5, Harbourgate Business Park, Southampton Road, Portsmouth PO6 4BQ, UK

Data di emissione:
Date of issue:

12/01/2021

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(Luca Bedonni - Technical Director)

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